

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Heidi Lopez de Diego et al.	Art Unit :	1624
Patent No. :	7,767,683	Examiner :	Emily Bernhardt
Issue Date :	August 3, 2010	Conf. No. :	6471
Serial No. :	10/568,572		
Filed :	August 14, 2006		
Title :	HYDROGEN SUCCINATE SALTS OF TRANS-4-((1R,3S)-6-CHLORO-3-PHENYLINDAN-1-YL)-1,2,2-TRIMETHYLPIPERAZINE AND THE USE AS A MEDICAMENT		

Commissioner for Patents
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APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(d)

Patentee hereby requests reconsideration of the Patent Term Adjustment (PTA) accorded the above-referenced patent. Reconsideration of the final PTA calculation to increase total PTA from 96 days to 155 days is respectfully requested.

REMARKS

(1) Measuring Overlap of “A Delay” and “B Delay”

“A Delays” are defined as delays by the U.S. Patent and Trademark Office (PTO) under 35 U.S.C. § 154(b)(1)(A), which guarantees prompt PTO response. “B Delays” are defined as delays by the PTO under 35 U.S.C. § 154(b)(1)(B), which guarantees no more than three year application pendency. To the extent that the periods of delay overlap, the period of any term adjustment shall not exceed the actual number of days the issuance of the patent was delayed. 35 U.S.C. § 154(b)(2)(A). As outlined in Wyeth v. Kappos, 591 F.3d 1364 (Fed. Cir. 2010), the only way that these periods of time can “overlap” is if they occur on the same day. If an “A delay” occurs on one calendar day and a “B delay” occurs on another calendar day, they do not overlap and 35 U.S.C. § 154(b)(2)(A) does not limit the extension to one day. *Id.*

CERTIFICATE OF MAILING BY EFS-WEB FILING

I hereby certify that this paper was filed with the Patent and Trademark Office using the EFS-WEB system on this date: October 1, 2010.

(2) Measuring “B Delay” for a National Stage Filing under 35 U.S.C. § 371

For a national stage filing under 35 U.S.C. § 371(b), application pendency must be measured from the date that marks the expiration of 30 months from the priority date of the international application (i.e., not from the date on which the application fulfilled the requirements of 35 U.S.C. § 371). The priority date of the instant patent is August 18, 2003; thus the date that is 30 months from the priority date is Saturday, February 18, 2006. As this date falls on a weekend, the expiration of the 30-month period extends to the following business day, or Tuesday, February 21, 2006 (given the President's Day holiday on Monday, February 20, 2006). Thus, the “actual filing date” for purposes of calculating “B Delay” under 35 U.S.C. § 154(b)(1)(B) and 37 C.F.R. § 1.702(b), is February 21, 2006.¹

REVIEW OF PATENT TERM ADJUSTMENT CALCULATION

“A Delay”

A first PTO action was due on or before October 14, 2007 (the date that is fourteen months after August 14, 2006, the date on which the application fulfilled the requirements of 35 U.S.C. § 371). See 37 C.F.R. §§ 1.702(a)(1) and 1.703(a)(1). The PTO mailed the first non-final Office Action on May 13, 2008, thereby according a PTO Delay of 212 days. Patentee does not dispute the PTO's calculation for this “A Delay.”

In view of the period of “A Delay” detailed above, the total “A Delay” for this patent should be calculated as 212 days.

¹ In contrast to reliance on “the expiration of 30 months from the priority date” for measuring “B Delay,” the beginning of the relevant period for purposes of calculating “A Delay” is the date on which an international application fulfills the requirements of 35 U.S.C. § 371. See 35 U.S.C. § 154(b)(1)(A)(i)(II) and 37 C.F.R. § 1.702(a)(1).

"B Delay"

The present application is a national stage filing under 35 U.S.C. § 371 of international application number PCT/DK2004/00545, filed August 18, 2004, which claims its earliest benefit of priority to United States Provisional Application No. 60/496,058, filed August 18, 2003, and Danish Application No. PA 2003 01180, filed August 18, 2003.

The national stage for the present application "commenced" under the provisions of 35 U.S.C. § 371(b), i.e., upon expiration of 30 months from the priority date of the international application.² As a result, and as discussed above, the date that the national stage commenced was February 21, 2006.

"B Delay" may not include the number of days in the period beginning on the date on which a Request for Continued Examination was filed and ending on the date the patent was issued. See 37 C.F.R. §§ 1.702(b)(1) and 1.703(b)(1). In addition, "B Delay" may not include the number of days in the period beginning on the date on which a Notice of Appeal was filed and ending on the date of mailing of a further Office Action or a Notice of Allowance. See 37 C.F.R. §§ 1.702(b)(4) and 1.703(b)(4).

In the present application, a Notice of Appeal was filed on July 16, 2009, a Request for Continued Examination was filed on February 16, 2010 (prior to the mailing of a further action by the Office), and the patent issued on August 3, 2010. Under these circumstances, the period beginning on the date the Notice of Appeal was filed (July 16, 2009) and continuing through patent issuance (August 3, 2010) must be excluded from the three year delay calculation.

The period beginning on February 22, 2009 (the day after the date that is three years after February 21, 2006, the date that the national stage commenced), and ending on July 15, 2009 (the day before the date that a Notice of Appeal was filed), is 144 days in length. As a result, the total "B Delay" for this patent should be calculated as 144 days. The PTO calculated 144 days of delay for issuance of a patent more than three years after filing. Patentee does not dispute the PTO's calculation of this "B Delay." See 37 C.F.R. §§ 1.702(b) and 1.703(b).

² A complete request for early processing under 35 U.S.C. § 371(f) was not filed with the present application.

Applicant : Heidi Lopez de Diego et al.
Patent No. : 7,767,683
Issued : August 3, 2010
Serial No. : 10/568,572
Filed : August 14, 2006
Page : 4 of 7

Attorney's Docket No.: 27507-0163001 / 453-US-PCT

Overlap of "A Delay" and "B Delay"

As detailed above, "A Delay" accumulated during the following period:

October 15, 2007, to May 13, 2008.

As detailed above, "B Delay" accumulated during the following period:

February 22, 2009, to July 15, 2009.

As such, the periods of "A Delay" and "B Delay" do not overlap (i.e., occur on the same calendar day).

Applicant Delay

(1) Points of Agreement with PTO Applicant Delay Calculation

(a) Late Reply to Office Action

A reply to an Office Action was due on or before August 13, 2008 (the date that is three months after May 13, 2008, the date on which the Office Action was mailed). Patentee filed a response to the Office Action on November 13, 2008, thereby accruing an Applicant Delay of 92 days. See 37 C.F.R. § 1.704(b). Patentee does not dispute the PTO's calculation for this Applicant Delay from August 14, 2008 (the day after the date that is three months after the date on which the Office Action was mailed), to November 13, 2008.

(b) Late Reply to Office Action

A reply to an Office Action was due on or before April 22, 2009 (the date that is three months after January 22, 2009, the date on which the Office Action was mailed). Patentee filed a response to the Office Action on July 16, 2009, thereby accruing an Applicant Delay of 85 days. See 37 C.F.R. § 1.704(b). Patentee does not dispute the PTO's calculation for this Applicant Delay from April 23, 2009 (the day after the date that is three months after the date on which the Office Action was mailed), to July 16, 2009.

(2) Points of Disagreement with PTO Applicant Delay Calculation

(a) Request for Corrected Filing Receipt After Allowance

Patentee filed a Request for Corrected Filing Receipt on May 24, 2010, subsequent to the mailing of a Notice of Allowance. As part of the request for correction of the filing receipt, Patentee also submitted a Supplemental Application Data Sheet containing the changes to be made by the correction. The Office responded to the filing on May 27, 2010, by issuing a Corrected Filing Receipt. In good faith and candor, Patentee notes that no Applicant Delay was accorded for this filing, and respectfully submits that a delay of 4 days for this post-allowance filing is appropriate, for delay occurring between May 24, 2010 (the date on which the post-allowance filing was made) and May 27, 2010 (the date on which the Office mailed its response). See 37 C.F.R. § 1.704(c)(10).

(b) Request to Correct Inventorship After Allowance

Patentee filed a Request to Correct Inventorship under 37 C.F.R. § 1.48 on June 2, 2010, subsequent to the mailing of a Notice of Allowance. As part of the request for correction of inventorship, Patentee also submitted a declaration by the inventors and a Supplemental Application Data Sheet containing the changes to be made. The Office responded to this filing on June 21, 2010, by issuing a Corrected Filing Receipt and Response to Rule 312 Communication. Applicant Delay of 20 days is appropriate for this post-allowance filing, for delay occurring between June 2, 2010 (the date on which the post-allowance filing was made) and June 21, 2010 (the date on which the Office mailed its response to all outstanding issues). See 37 C.F.R. § 1.704(c)(10).

A review of the PAIR/PALM system reveals that two entries of Applicant Delay of 20 days each have been entered with regard to the submissions summarized above, apparently running concurrently from the date of filing of the Request to Correct Inventorship (June 2, 2010) and ending on the date of the Office's response thereto (June 21, 2010). However, only one period of delay of 20 days is appropriate for this post-allowance filing, since

all of the papers filed on June 2, 2010 were related to the Request to Correct Inventorship and the Office's response on June 21, 2010 constituted a response to all of the papers filed on June 2, 2010. Furthermore, 37 CFR 1.704(c) explicitly prohibits the Office from double counting periods of Applicant Delay, stating that "[c]ircumstances that constitute a failure of the applicant to engage in reasonable efforts to conclude processing or examination of an application also include the following circumstances, which will result in the following reduction of the period of adjustment set forth in § 1.703 to the extent that the periods are not overlapping" (emphasis added). In the present circumstance, the Office improperly double-counted a single 20 day period (from June 2, 2010 to June 21, 2010) as triggering 40 days of Applicant Delay. In view of the foregoing remarks, Patentee respectfully requests that the period of delay from June 2, 2010 to June 21, 2010 be adjusted to 20 days.

(c) Request to Change Address After Allowance

Patentee filed a Supplemental Application Data Sheet on June 22, 2010, subsequent to the mailing of a Notice of Allowance. The only changes requested on the Supplemental Application Data Sheet were changes to the email address of the practitioner and an inventor's mailing address. Although the filing of a paper to change an address is not mentioned in 37 C.F.R. § 1.704(c)(10), such a filing is specifically addressed in the section of MPEP 2732 that clarifies the types of papers filed after allowance that are not considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application under 37 C.F.R. § 1.704(c)(10). According to MPEP 2732, papers filed after allowance that are "**not** considered to be a failure to engage in reasonable efforts to conclude processing or examination of an application [include] ... (4) Change of Address" *Id.* Because the Supplemental Application Data Sheet filed on June 22, 2010 related only to changes of address, an assessment of Applicant Delay for this filing is inappropriate. The PAIR/PALM system indicates 43 days of Applicant Delay were accorded in association with this change of address filing. In view of the foregoing remarks, Patentee respectfully submits that 0 days of Applicant Delay should be accorded to the filing.

Applicant : Heidi Lopez de Diego et al.
Patent No. : 7,767,683
Issued : August 3, 2010
Serial No. : 10/568,572
Filed : August 14, 2006
Page : 7 of 7

Attorney's Docket No.: 27507-0163001 / 453-US-PCT

(3) Summary of Proper Applicant Delay Calculation

In view of the periods of Applicant Delay detailed above, the total Applicant Delay for this patent should be calculated as 201 days (i.e., the sum of 92 days, 85 days, 4 days, and 20 days).

Terminal Disclaimer

This patent is not subject to a terminal disclaimer.

Conclusion

In consideration of the events described above, Patentee believes the PTA calculation of 96 days is incorrect. As such, Patentee respectfully requests reconsideration of the PTA in the following manner:

- 1) Total PTO Delay should be calculated as 356 days (i.e., the sum of 212 days of "A Delay" and 144 days of "B Delay");
- 2) Total Applicant Delay should be calculated as 201 days; and
- 3) Total PTA should be calculated as 155 days.

The fee of \$200 required under 37 C.F.R. § 1.18(e) is being submitted herewith. Please apply any other required charges or credits to Deposit Account No. 06-1050, referencing attorney docket number 27507-0163001.

Respectfully submitted,

Date: October 1, 2010

/Jack Brennan/
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